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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,257	02/15/2002	Yoram Reiter	02/23338	9820
7590	07/28/2004		EXAMINER	
SOL SHEINBEIN c/o ANTHONY CASTORINA SUITE 207 2001 JEFFERSON DAVIS HIGHWAY ARLINGTON, VA 22202			VANDERVEGT, FRANCOIS P	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 07/28/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/075,257	REITER, YORAM
Examiner	Art Unit	
F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 22 April 2004.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-14 is/are pending in the application.  
4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 5-14 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

**DETAILED ACTION**

This application is a continuation of U.S. Application Serial Number 09/534,966.

Claims 1-14 are currently pending.

***Election/Restrictions***

1. Applicant's election of Group III, claims 5-14, drawn to a method of producing a functional MHC class I molecule in a bacterial cell, in the reply filed on April 22, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
  
2. **Claims 1-4 are withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on April 22, 2004.

**Claims 5-14 are the subject of examination in the present Office Action.**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 5-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al (Proc. Nat. Acad. Sci. (USA) [1993] 90:10330-10334; U on form PTO-892) in view of Matsumura et al (J. Biol. Chem. [1992] 267(33): 23589-23595; V on form PTO-892).

Altman teaches a method for the production of soluble functional MHC class II complexes in *E. coli* (see entire document). Altman teaches the purification of MHC class II from inclusion bodies and the in vitro refolding of the MHC molecules. Altman teaches the association of the MHC molecules with antigenic peptides. Altman teaches that no other proteins are required for the efficient folding of the MHC molecules and that carbohydrate modification is not necessary for T cell recognition. Altman teaches that production in *E. coli* provides large quantities of MHC molecules needed for conformational and functional studies (page 10334 in particular). Altman teaches that production of empty MHC class I

molecules is possible, but is inhibited by the instability of the complex at physiological temperatures (page 10334 in particular).

Altman does not teach the production of MHC class I molecules.

Matsumura teaches the production of soluble empty MHC class I molecules in *Drosophila melanogaster* cells and the binding of peptides to the complexes (see entire document).

It would have been *prima facie* obvious to a person having ordinary skill in the art at the time the invention was made to use the method of Altman to produce the MHC class I molecules of Matsumura in *E. coli*. One would have been motivated to combine the teachings with a reasonable expectation of success by the teaching of Altman that MHC molecules do not need accessory molecules for folding and that they do not need glycosylation to be functional. One would have been further motivated by the teaching of Matsumura that empty MHC class I molecules are stable at lower temperature and can be loaded with antigenic peptides. It is well known in the art that *E. coli* can be easily cultivated at temperatures at least as low as 4 degrees C. Accordingly, the artisan would have expected to be able to produce large quantities of functional MHC class I molecules at a low cost through use of the combined methods.

### *Conclusion*

4. No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. *PR*  
Patent Examiner  
July 26, 2004

*Patrick J. Nolan*  
PATRICK J. NOLAN, PH.D.  
PRIMARY EXAMINER  
*7/26/04*